ISRCTN11877533 https://doi.org/10.1186/ISRCTN11877533

Does adding an oral cortisone pill to the regular treatment of patients with rib cage pain and swelling improve their pain and quality of life?

Submission date
18/04/2022

Recruitment status
No longer recruiting

Registration date
30/04/2022

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tietze syndrome is a rare form of chest wall inflammation with joint swelling which can cause significant chest pain and a decline in the ability of daily activities. It can be easily confused with other serious diseases that affect the heart, lung and chest wall. It can be a frequent cause for visiting the emergency department or outpatient clinic. There is no standardized treatment protocol. The aim of this study was to assess the efficacy of adding oral steroids in addition to other non-steroidal treatment in the improvement of pain and quality of life in patients with Tietze syndrome.

Who can participate?
Patients aged 12 to 60 years old presenting with anterior or posterior chest wall swelling and/or palpable tenderness upon examination without any significant past medical history, or with history of recurrent chest infection or multiple minor chest trauma.

What does the study involve?
Participants will be randomly allocated to receive treatment as usual or an oral corticosteroid in addition to treatment as usual for 3 weeks. Follow up is for up to 12 months.

What are the possible benefits and risks of participating?
Benefits include improvement in pain and quality of life with the intervention
Risks include the adverse effects of oral corticosteroids which will be monitored by the study

Where is the study run from?
Thoracic surgery department, Ain Shams University (Egypt)

When is the study starting and how long is it expected to run for?
February 2020 to April 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Hany Hassan Elsayed, hanyhassan77@hotmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Prof Hany Hasan Elsayed

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The efficacy of oral corticosteroids for treatment of Tietze syndrome: a pragmatic randomized controlled trial

Acronym
OCTA

Study objectives
Oral corticosteroids may provide an additional benefit for patients with Tietze syndrome

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 15/02/2020, Ain Shams University hospital ethical committee (Abbasia square, Cairo C237765, Egypt; no telephone number provided; Ethicalcommitee@ainshams.edu.eg), ref: 08 /ASU01/47

Study design
Single center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Teitze syndrome: costochondritis of the chest wall with joint swelling

Interventions
The intervention group will have oral corticosteroid therapy for a short period in addition to all conventional methods of treatment.
The control group will have only the conventional treatment

Total duration of treatment = 3 weeks

Follow up period for the steroid arm 1-12 months, median 5.5 months

Follow up period for the NSAID arm 1-12 months, median 7 months

Median follow up period 6.5 months

Randomisation process by sealed envelope

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
oral prednisolone

Primary outcome measure
1. Pain measured using the NRS at 1, 2, 3 weeks and follow up period
2. Quality of life measured using the EURO 5Q-5D-5L score at 3 weeks

Secondary outcome measures
Size of joint swelling measured by patient interview at 3 weeks and 6 months after treatment.

Overall study start date
15/02/2020

Completion date
01/04/2022

Eligibility

Key inclusion criteria
Patients aged 12 to 60 years old presenting with anterior or posterior chest wall swelling and/or palpable tenderness upon examination without any significant past medical history, or with history of recurrent chest infection or multiple minor chest trauma. Ultrasound of the sternocostal swellings was required to exclude other pathologies but no specific ultrasound finding was required to confirm the clinical diagnosis. Two senior thoracic surgeons were required to establish the diagnosis.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Patients diagnosed with myositis, coronary syndrome, chest wall tumors or mediastinal syndrome as diagnosed by clinical examination, CT chest, MRI chest or chest ultrasound.
2. Traumatic muscle pain, arthritis of sternoclavicular/sternomanubrial joints and fibromyalgia of costochondral junction.
3. Refused to be enrolled in the study or did not complete the full assessment at all time intervals.

Date of first enrolment
01/08/2020

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
Egypt

Study participating centre
Thoracic surgery department, Ain Shams University
Abbasia square
Cairo
Egypt
C234

Sponsor information

Organisation
Ain Shams University

Sponsor details
15 9th area buildings
Cairo
Egypt
C237776
+20 1227373270
projectscenter@ainshams.edu.eg

Sponsor type
Not defined

Website
http://www.asu.edu.eg/

ROR
https://ror.org/00cb9w016

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2022

Individual participant data (IPD) sharing plan
Data is available upon request from hanyhassan77@hotmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/11/2022	29/11/2022	Yes	No